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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,545

08/21/2003

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12/19/2008

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

12/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,545	Applicant(s) HINE ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-13 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 8, 2008 has been entered.

Response to Arguments

Applicant's arguments with respect to claims 1-6 and 11-13 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the first electrical contact element has an "outer surface forming a portion of the first external surface", when the first electrical contact element is "positioned along the first inner surface" (as recited in claim 1).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1, 3-4, 6, 11-13 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses a pacemaker with a connector bore for electrically and mechanically connecting the implantable medical device (IMD) with two adapters and multi-electrode leads as displayed in figures 6 and 7. The adapters upsize the leads prior to the insertion into the connector bore within the IMD. The array of lead connector elements are displayed in figure 2 as “sleeves 151 and 152 (in contact with

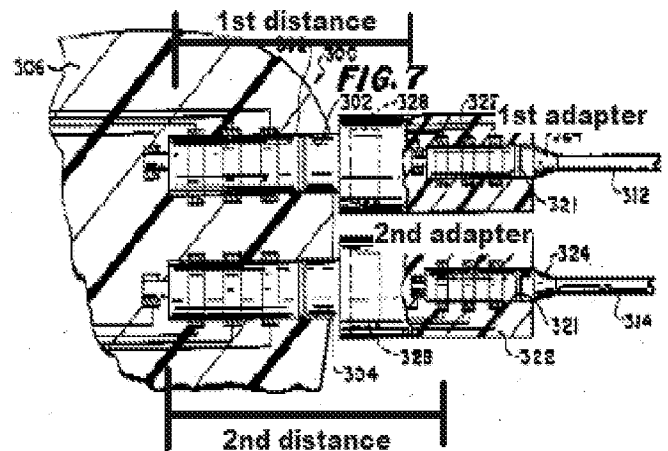
rings 141 and 142) (col. 7, lines 63-64)". The sleeves are connected to electrodes, with a conductor for each electrode. The two adaptors, which the examiner considers to be a plurality of adaptors, have an inner lumen for engaging the sleeves of the lead with rings to create an electrical and mechanical connection. In addition, the adaptors have an external surface used for engagement with the electrical bore. This engagement surface has two contact zones, the pin as the first zone and sleeves of the lead as the second zone, which connects within the IMD with the socket and rings, respectively.

Since the lead connectors are located circumferentially around the lead, the examiner considers the connectors to be connector rings. In addition, a connector ring is located adjacent to the sealing ring and distal to the remainder of the array of lead connectors. Therefore, since the ring conductor makes contact with the bore of the IMD by means of the adaptor, the connector ring is located distal to the array of lead connector elements and electrically connected to the IMD bore.

Within the adaptor-lead connector, there are two sealing rings. One sealing ring, as previously mentioned, is located distal to the array of connector elements located on the lead. The other sealing ring is located on the adaptor located proximal to the array of connector elements.

Outer surface of a male connector piece closely matched the inner surface of a female connector piece the connection assembly is dimensioned to be press fit. Therefore, since the sleeves or array of lead connector elements on the cylindrical male piece closely match the rings or contact elements located within the adaptor on a cylindrical female piece, the connection assembly is press fit.

As to claims 1 and 11, the examiner has included a replication of figure 7 to display the first and second distances. The examiner considers the first distance is to the first contact zone and the second distance is to the second contact zone. Therefore the first distance is not equal to the second distance.



Furthermore, as to claim 1, Pohndorf et al. discloses two adapters, as seen in figures 6 and 7, sized to engage in the connection bore of the IMD. Both of the adapters have internal surfaces which form lumens sized to receive a single lead. Specifically “the second adapter ...forming a second lumen to receive the single lead”. Therefore, Pohndorf et al. meets the limitation by disclosing two adapters with lumens sized or formed to receive the single lead

Additionally, Pohndorf et al. discloses in col. 6, line 31, the header 38 is made of insulative material. Since the header, which is configured to be in electrical contact with the adapter(s), is made of insulating material it is understood that the adapters, which are in electrical contact with the leads, would also inherently be made of similar material. Constructing the header and adapters from insulative material assured that the electrical contacts will not engage with the lead until the lead is properly inserted and aligned (see figure 5 and 7). Thus the examiner considers Pohndorf et al. to necessarily possess an insulative sleeve within the inner adapter lumen.

In the alternative, although the examiner considers Pohndorf et al. to disclose an insulative sleeve within the inner adapter lumen, it would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate an insulative inner sleeve to provide the predictable results of preventing improper electrical engagement, as well as, assuring that the electrical charge is directed to the header 38 and not dissipated by the adapter. The incorporation of an insulative sleeve would also prevent the adapter from functioning like an electrode.

Additionally, it is well known in the art to employ an insulative sleeve into an adapter lumen or header lumen in order to prevent unnecessary or unwanted electrical engagement with a lead.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934). Pohndorf et al. discloses the claimed invention except for the external surface conforming to industry standard. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the external surfaces as taught by Pohndorf et al. with external surfaces conforming to industry standard since it was known in the art to construct medical devices to an industry standard to provide the predictable results of ensuring quality and uniformity.

3. Claim 5 is rejected under 35 U.S.C. 103(a) as being obvious over Pohndorf et al. (US 4,628,934) in view of Peers-Trevarton (US 4,469,104). Holleman et al. discloses the claimed invention except for the protrusions for each contact element within the array of lead contact elements. Peers-Trevarton teaches that it is known to utilize protrusions and depressions to securely mechanically and electrically engage the lead.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical connections of the lead as taught by Pohndorf et al. with the electrical and mechanical connections as taught by Peers-Trevarton since such a modification would be a substitution of known functional equivalents by substituting electrical connectors which would provide the predictable results of electrically engage the lead.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762